## REMARKS

Applicant thanks the Examiner and her Supervisor, Joseph Thomas, for the courtesies extended to Applicant's representative, Melvin Garner, during the personal interview conducted on October 29, 2003. This Supplemental Amendment is in response thereto.

During the interview it was agreed that Applicant's arguments regarding the applied prior art had merit, but the Examiners did not believe the asserted features to be positively recited in the claims. The claim amendments set forth herein are intended to address the Examiners' concerns. Applicant also has the following additional comments.

Contrary to the Examiner's statement in the Office Action on page 5, last paragraph, DeBusk does not teach the standardization of a prior clinical trial being stored in a database in the form of a software template. Rather, DeBusk stores modular, reusable, standard software modules that are selectable to represent a future clinical procedure to be conducted.

The Examiner states on page 6, second paragraph, of the Office Action that the motivation to combine DeBusk with Colon is to provide an integrated information system for managing, optimizing, and analyzing resources within a health-care institution using a modular software structure. But this is not the present invention's purpose, which is designing future clinical trials.

Contrary to the Examiner's statement in the Office Action on page 6, last paragraph, Colon does not teach a main processor and main database in an organizationa. environment that includes other databases with information for formulating clinical trials. Colon has a database host computer 11 used to store study data in separate tables. Tables are joined as needed to produce databases for statistical analysis. (See Colon, col. 3, lines 14-23.) These databases do not include information for formulating clinical trials. As asserted previously, Colon relates to the conduction of an already-designed clinical trial, and thus has no need for databases with information for formulating clinical trials.

DeBusk does not include a human resources database of personnel or location information, as asserted by the Examiner in the Office Action on page 7, second full paragraph, and on page 14, third full paragraph. The databases in DeBusk are merely databases of supplies. (See DeBusk, col. 14, line 55.)

Contrary to the Examiner's statement in the Office Action in the paragraph bridging pages 7 and 8, claim 43 does not differ from claim 19 in the manner suggested by the Examiner. That is, contrary to the Examiner's statement, claim 19, like claim 43, recites that the user processor and main processor run a program permitting the design of a clinical trial in the form of a protocol of tasks to be completed and the tracking of the completion of the tasks in the protocol at the user processor.

Furthermore, neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and tracking the completion at a user processor. (See Office Action, page 8, last paragraph.) Colon merely updates prescriptions and sends the results to a host computer database. DeBusk does not track completed tasks, not to mention at a user processor.

Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor. (See Office Action, page 10, paragraph 4.) As stated numerous times, the applied references do not suggest the design of a clinical trial.

Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database, as suggested by the Examiner on page 12, second to last paragraph, of the Office Action. In fact, Edelson states in column 48, lines 5-7, that each data warehouse maintains replicated copies of data sets obtained by read-only access of remote databases.

The applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location, as suggested by the Examiner on page 12, last paragraph, of the

Office Action. Colon merely discloses subjects being located at different geographic sites, and Edelson discloses looking at patient prescription activity in a limited geographical region.

Contrary to the Examiner's statement on page 13, first full paragraph of the Office Action, neither Colon nor DeBusk suggest that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto. Again, the applied references do not suggest the design of a clinical trial, and thus there is no updating of a protocol.

The Examiner states in the Office Action, page 13, last paragraph, that Edelson teaches transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring to and updating the main database with the modified copy of the data and unlocking that portion of the main database. Applicant respectfully disagrees. While access protocols are mentioned in Edelson in column 8, lines 47-50, there are no details regarding locking and unlocking portions of any databases.

Contrary to the Examiner's statement on page 16, fourth full paragraph, Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location. Rather, Edelson states in column 48, lines 5-7, that each data warehouse maintains replicated copies of data sets obtained by read-only access of remote databases.

Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as asserted by the Examiner in the Office Action on page 17, third paragraph, and on page 20, third paragraph.

Umen merely displays a tabular list of protocols, with none of the protocols indented. (See Umen, col. 10, lines 23-31.)

Further, none of the applied references suggests the program automatically indicating the completion of a common major task in separate protocols when all of the minor related tasks are completed, as asserted by the Examiner in the Office Action on page 19, paragraph 3, and on page 21, third full paragraph. Colon merely discusses updating modified prescription data; there are no major or minor tasks disclosed. Umen discusses integrating data from more than one study, but again, there is no discussion of major and minor tasks, not to mention an indication of completion of a common major task in separate protocols. Edelson does not disclose anything close enough to this feature upon which to even comment here.

The Examiner takes Official Notice on page 22, second paragraph, and on page 23, last paragraph, that sending a message to a provider of supplies to inform it of supplies needed is allegedly well known in the art. Applicant respectfully submits that there is no known module that generates a message to a provider of supplies to inform it of supplies needed. Applicant therefore respectfully requests the Examiner to either provide support for her position or withdraw this rejection.

Thus each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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